USER MANUAL

MEDLINE®
IMPROVING EFFICIENCY

CARELINE®
IMPROVING EFFICIENCY

Clean Me & Check Me

To learn more about LINAK please visit:

WWW.LINAK.COM

LINAK®
WE IMPROVE YOUR LIFE

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Preface

We are delighted that you have chosen a product from LINAK®.

LINAK systems are high-tech products based on many years of experience in the manufacture and development of actuators, electric control boxes, controls and chargers.

This User Manual will tell you how to install, use and maintain your LINAK electronics.

We are sure that your LINAK system will give you many years of problem-free operation. Before our products leave the factory they undergo full function and quality testing. Should you nevertheless experience problems with your systems, you are always welcome to contact your local dealer.

LINAK subsidiaries and some distributors situated all over the world have authorized service centres, which are always ready to help you.

LINAK provides a warranty on all its products. This warranty, however, is subject to correct use in accordance with the specifications, maintenance being done correctly and any repairs being carried out at a service centre, which is authorized to repair LINAK products.

Changes in installation and use of LINAK systems can affect their operation and durability. The products are not to be opened by unauthorized personnel. The User Manual has been written on the basis of our present technical knowledge. We are constantly working on updating the information and we therefore reserve the right to carry out technical modifications.

LINAK A/S

Important information

Description of the various signs used in this manual.

Warning!

Failure to comply with these instructions may result in accidents involving serious personal injury.

Failing to follow these instructions can result in the product being damaged or destroyed.

Safety instructions

Safe use of the system is possible only when the operating instructions are read completely and the instructions contained are strictly observed.
Failure to comply with instructions marked with the"NOTE" symbol may result in serious damage to the system or one of its components.
Persons who do not have the necessary experience or knowledge of the product/products must not use the product/ products. Besides, persons with reduced physical or mental abilities must not use the product/products, unless they are under surveillance or they have been thoroughly instructed in the use of the apparatus by a person who is responsible for the safety of these persons.
Moreover, children must be under surveillance to ensure that they do not play with the product.

It is important for everyone who is to connect, install, or use the systems to have the necessary information and access to this User Manual.

If there is visible damage to the product it must not be installed.

The appliance is not intended for use by young children or infirm persons without supervision.

Young children should be supervised to ensure that they do not play with the appliance.

Residual risk
Some of the products contains software based components. LINAK has done various possible efforts to assure that the software is free of errors and that the software has been developed according to the rules of IEC 60601-1-4 (software in Medical products). That involves Risk Analysis which shows a small residual risk for unwanted/unintended movement of actuators under specific conditions.
According to the above rules it must be informed and if necessary considered in the Risk analysis of the final application - More details to residual risk can be provided by LINAK if necessary.

Warning!
The plastic parts in the system cannot tolerate cutting oil.

Warning!
LINAK's actuators and electronics are not constructed for use within the following fields:
- Planes and other aircrafts
- Explosive environments
- Nuclear power generation

Warnings:
If faults are observed, the products must be replaced.
Never spray directly on the products with a high-pressure cleaner.

The LINAK products cannot tolerate the influence of strong solvents, basic or alkaline liquids.

Before installation, re-installation, or troubleshooting
- Stop the application
- Switch off the power supply and pull out the mains plug.
- Relieve the application of any loads, which may be released during the work.

Before start-up
- Make sure that the system has been installed as instructed in the User Manual.
- Make sure that the voltage of the control box is correct before the system is connected to the mains.
- System connection. The individual parts must be connected before the control box is connected to the mains.

During operation
- Ensure that the cables are not damaged.
- Unplug the mains cable on mobile equipment before it is moved.

Repairs

In order to avoid the risk of malfunction, all repairs must only be carried out by authorized LINAK workshops or repairers, as special tools must be used and special gaskets must be fitted. Products under warranty must also be returned to authorized LINAK workshops.

Warning!
If any of the LINAK products are opened, there will be a risk of subsequent malfunction.

Disposal of LINAK's products
LINAK's products may be disposed of, possibly by dividing them into different waste groups for recycling or combustion.

We recommend that our product is disassembled as much as possible at the disposal and that you try to recycle it. As an example of main groups within sorting of waste we can mention the following:

Metal, plastic, cable scrap, combustible material and collection for recoverable resources.

Some of these main groups can be sub-divided into groups e.g. metal can be divided into iron, stainless steel and aluminium and alloy steel. Plastic can e.g. be divided into ABS, PA, PE and PP.

The Clean Me & Check Me can be disassembled and sorted into the following recycling groups:

Clean Me & Check Me	Plastic housing – Plastic recycling or combustion
	Cable – Cable scrap or combustion
	PC-board – Electronics Scrap

By now all our casted plastic units are provided with an interior code for plastic types and fiber contents, if any.

CE

LINAK®

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DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY

LINAK A/S
Smedevænget 8
DK - 6430 Nordborg

Name and address of the person authorized to compile the relevant technical documentation:
John Kling, Group Headquarters, Guderup, DK-6430 Nordborg, email jkl@linak.com

Herewith declares that LINAK Actuators and Actuator Systems comply with the following parts of the Machinery Directive 2006/42/EC, ANNEX I, *Essential health and safety requirements relating to the design and construction of machinery*:
1.5.1 Electricity supply: *Directive 2006/95/EC on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits.*
1.5.10 Radiation, 1.5.11 External radiation: *Directive 2004/108/EC on the approximation of the laws of the Member States relating to electromagnetic compatibility.*

The relevant technical documentation is compiled in accordance with part B of Annex VII and that this documentation or part hereof will be transmitted by post or electronically to a reasoned request by the national authorities.

This partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of this Directive, where appropriate.

Date: 2010-01-01

Signature:

John Kling

John Kling
Certification and Regulatory Affairs

Misc. on the Clean Me & Check Me system

Warranty and service life

The LINAK warranty covers manufacturing defects in the products, starting from the date of manufacture. There is 18 months' for MEDLINE and CARELINE products. The warranty is limited to the value of the LINAK product.

LINAK's guarantee is only valid so far as the products have been used and maintained correctly and has not been tampered with. Furthermore, the products must not be exposed to violent treatment. In the event of this, the warranty will be ineffective / invalid. LINAK's warranty is only valid if the system is unopened and has been used correctly.

All LINAK products are designed to have an optimum service life as a matter of course, but the expected service life in a specific application is very dependent on how the products are used.

Maintenance

- The LINAK products must be cleaned at regular intervals to remove dust and dirt and inspected for mechanical damage, wear and breaks.
- The LINAK Clean Me & Check Me are closed units and require no internal maintenance.
- IP 66 Washable tolerates being washed in tunnels.
- The LINAK products must be IP 66 washable when cleaning in wash tunnels. Make sure that the plugs are correctly fitted with O-rings before washing.
- O-rings: When individual parts are replaced in a LINAK IP66 or IP66 washable system, the O-rings on all parts, must be replaced at the same time. On control boxes with a replaceable mains fuse, the O-ring in the fuse cover must be replaced every time the cover has been removed. The O-rings must be greased in water free Vaseline when replacing them. Make sure that the counterpart - the socket - is clean and undamaged.
- Electronics must be inspected at attachment points, wires, cabinet, and plugs.
- Inspect the connections, cables, cabinet, and plugs, and check for correct functioning.

IP Protection degree:

All LINAK products can be cleaned as followed according to their IP protection which is stated on the product label.

IP Protection	Cleaning instrucions
IPX0	Clean with a damp cloth.
IPX1	Clean with a damp cloth.
IPX2	Clean with a damp cloth.
IPX3	Clean with a damp cloth.
IPX4	Clean with a damp cloth.
IPX5	Wash with a brush and water, but not water under pressure.
IPX6	X Wash with a brush and water. The water can be under pressure, but the system must not be hosed down directly with a high pressure cleaner. Max. 20°C.
IPX6	Washable* Clean by the use of water tunnels.

X can have a value of between 1 and 6.

** The following products can be marked with IP x6, but they are still allowed for wash tunnels : ACP, ACM (mini), ACM (new), BA18, CB12/14, DJB, FS2, HB40, LA28, LA32, LA34 stand., LA34 comp.*

The materials are resistant to the majority of cleaners and disinfectants used in the hospital and nursing home sector.

Cleaning with a steam cleaner, for example, is not permitted, as it will not be possible to maintain a minimum distance of 300 mm from the electrical parts.

IP66 Washable products can be washed in wash tunnels that washes according to the "Maschinelle Dekontamination" provided that the following guidelines are complied with:

- The cleaning and disinfection cycle in the wash tunnel must not last longer than 10 minutes.
- The nozzle pressure in the wash tunnel must not exceed 10 bar.
- The distance between the nozzle and the electrical parts must be at least 300 mm.
- The handset and motor plug must be pushed right in.
- The water temperature must not exceed 65°C.
- Cooling with cold water is not permitted.

To avoid degreasing of the piston rod, the actuator should be retracted to minimum stroke before washing.

The following directions regarding cleaners and disinfectants must be complied with:

- They must not be highly alkaline or acidic (pH value 6-8).
- They must not contain caustic agents.

- Their contents must not be able to change the structure of the surface or adhesion of the plastic.
- They must not break down grease.

The following disinfectants/detergents are recommended:
- Neodischer Dekonta, dosage 1-3%, made by CHEMISCHE FABRIK Dr. WEIGERT
- CCOTRADE RW, dosage 0.5%, made by CCOTRADE GmbH.

Warning!
The systems must not be sprayed directly with a high-pressure cleaner.

Mounting information:
- The Clean Me/Check Me must be mounted vertically (in order to maintain the IP degree)

Gore-tex membrane.
At the rear of the product housing there is a gore-tex membrane if this becomes damaged LINAK cannot guarantee the IP degree.

Environmental conditions:

Environment conditions	
Operating:	
Temperature Relative humidity Atmospheric pressure	5°C to 40°C 20% to 90% @ 30°C – not condensing 700 to 1060 hPa
Storage:	
Temperature Relative humidity Atmospheric pressure	-10°C to +50°C 20% to 90% @ 30°C – not condensing 700 to 1060 hPa

Valid where nothing otherwise is stated under the specific products in a later section.

Insulation class:

LINAK control boxes are available in insulation class 1 and insulation class 2.

Class 1 means with earth connection

Class 2 means without earth connection

When measuring the resistance in the earth connection in LINAK Control Boxes (class 1), it is recommended to use equipment, delivering a test current of no less than 5A. The resulting voltage will correspond to the resistance in the earth connection. Test currents below 5A, would yield no exact measurements.

Key to symbols

The following symbols are used on the label on the LINAK products.

Type B equipment, as per EN 60601-1

Protection against contact/foreign matter (first character) and water (second character) as per EN60529

Class 2 equipment

For indoor use

Double insulated transformer

Protective earth

Alternating Current

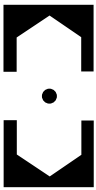
Direct current

Attention, consult accompanying documents

Lock function

Release function

Charge indicator



Safety switch/enable button

Demko approval

Fimko approval

APPROVAL V94265 Australian approval mark

APPROVAL NO.:97122 Australian approval mark

Recognised - Component Mark

Canadian Recognised - Component Mark

Recognised Component Mark for Canada and the United States

T-Mark

RW-Tüv approval

Tüv.Produkt Service

TÜVRheinland

ETL

C-ETL

CS95145V

LGA

UL Listing Mark

C-UL Listing Mark

C-UL US Listing Mark

UL Listing Mark

File E97199 UL file number

File E175209 UL file number

File E151104 UL file number

CSA

PSE-Mark

Product with a thermofuse

For indoor use (House).

Safety isolating transformer.

Electronics scrap

Equipment Kl.2 (Double square)

Patient part of type B (Mand)

Patient part of type BF

Earth protection

KL.1 Equipment class1.

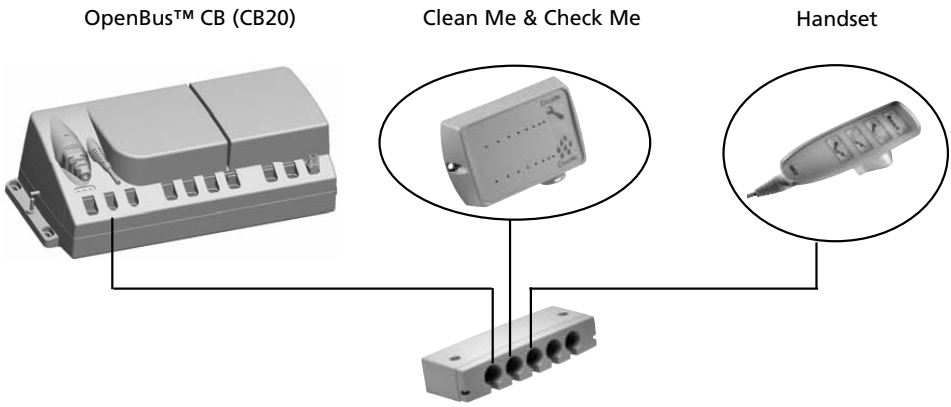
Earth

CE Mark

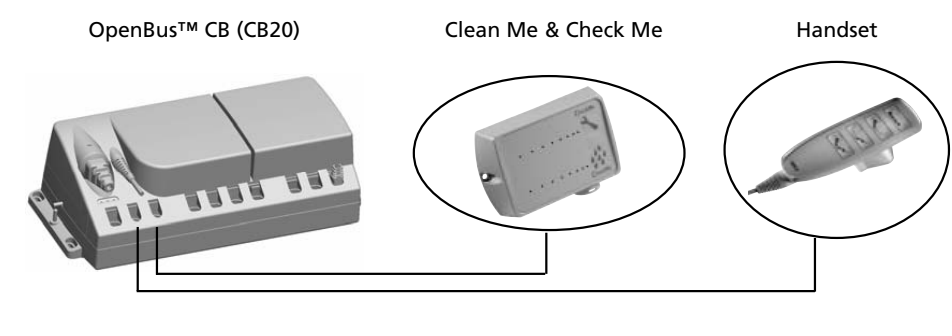
C-TICK

Discription of the LINAK Clean Me & Check Me system:

How to connect Clean Me & Check Me:

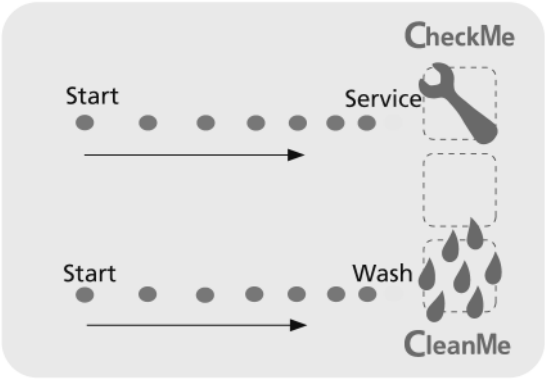


Alternatively:



Functionality of the user interface:
Clean Me and Check Me are single user interfaces that can also be combined into one. When a diode is alight it indicates the time or number of washes to the next cleaning or service, e.g. if the Clean Me is set to be cleaned every 14 days the diode will start at the first green diode on the left, and every second day (8 diodes from start until time of cleaning) move towards the yellow diode 8 indicating that it is time to clean the bed.

These interval settings can be adjusted both for Clean Me and Check Me.



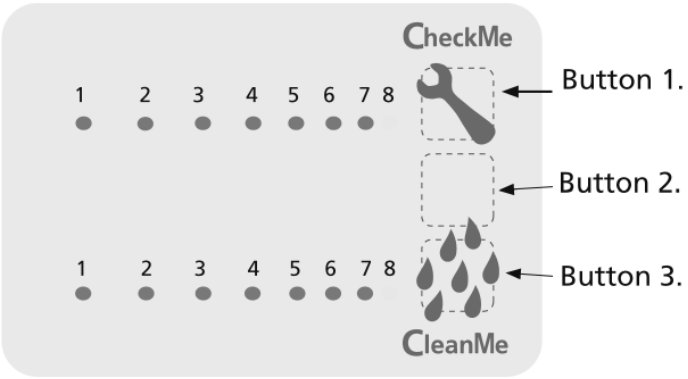
The diodes will only be alight as long as the application is connected to the mains. The battery backup will supply the necessary power to keep the Clean Me/Check Me functional (counting) just not visible (diodes not lit). If the OpenBus control box that the Clean Me/Check Me is connected to has a battery then you will be able to activate the diodes for a short period of time when pressing a button on the Control connected to the application on the Clean Me / Check Me.

- It is possible to wake up the Clean ME / Check Me in two ways, to see the diode status.
  1. push a button on the CleanME/CheckME this will wake up the CleanMe/CheckME for 1 min., but it will not wake up the CB
  2. Push a button on a Control (HB, ACO) this will wake up the CB and the Clean ME / Check Me for 2 min. (Vbus power down time) + 1 min. (CME power down time).

12 years “end of life” indication.

- If the start and Service/Wash diodes start to blink the Clean Me/Check me is out of battery power. The battery is not replaceable, the Clean Me/Check Me must be replaced.

Reset procedure of Clean Me / Check Me.



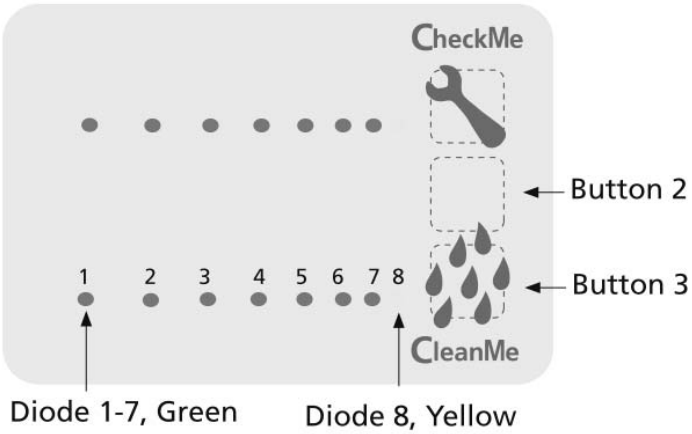
Manual Reset:

- Button 1 (check Me) / Button 3 (Clean Me) is held down for 5sec.
- Diode 8 begins to blink, release buttons 1 or 3 and press down again in order to reset.
- The Check Me / Clean Me is ready for use. Diode 1 lights.

Automatic Reset after wash (wash tunnel):
With the built-in wash/temperature sensor the Clean Me / Check Me detects a wash when the temperature reaches 50°C, and counts the wash for Check Me and resets Clean me when the temperature drops below 40°C again.

Read out:
It is possible to read out the actual interval setting.Push button 1 + 2 (Check Me) or 2 + 3 (Clean ME) for 10 sec.The last saved settings will be shown. If you do not want to change the settings, don’t make any further selections on the buttons 1, 2 or 3. wait until the Clean Me / Check Me confirm by blinking with the diodes shown.

User interface configuration Clean Me:



Interval adjustment:

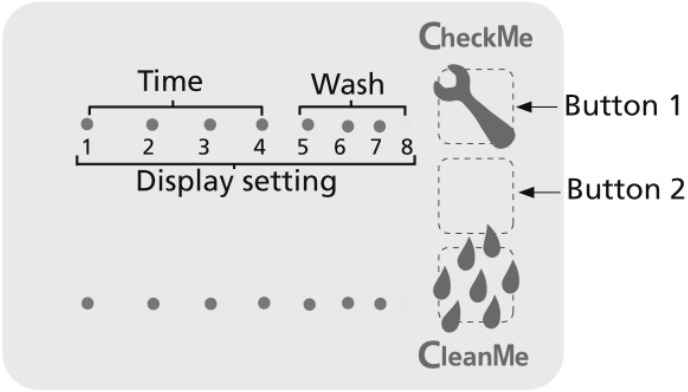
- Both buttons 2+3 are pressed down for 10 sec.
- Thereafter one of the diodes will start to blink. It will always show the last used setting. (4 = default first time)
- Press button 3 and the diode changes direction towards diode number 1. (After reaching diode 1 it will start again at diode number 8).

8.diode Wash now
7.diode Wash after 3 days
6.diode Wash after 7 days
5.diode Wash after 10 days
4.diode Wash after 14 days (default installation)
3.diode Wash after 18 days
2.diode Wash after 21 days
1.diode Wash after 30 days

- If no button is pressed for 5 sec. the chosen diode blinks 3 times to confirm the setting.
- The Clean Me system is ready for use. The chosen interval is not updated before you have followed the reset procedure on page 9.
- Pressing buttons 2+3 during the interval adjustment, will bring you back to the starting point again (last saved setting).

User interface configuration Check Me:

The interval setting between inspections can be adjusted on demand choosing both services after washes and after time. It is your choice which setting you want displayed after the interval adjustment.
Using the default settings as an example: The user interface Check Me is set to service after 25 washes and 12 months. It is the number of washes before service that the display will show (moving from 1– 8 where, 8 = time for service).
With default settings the service diode will light after 12 months are reached before the bed has been washed 25 times the displayed light will move to diode 8 to indicate time for service.



Service Interval adjustment is carried out in 3 steps:
Step 1.

- Both buttons 1 + 2 are pressed down for 10 sec.
- Thereafter one of the diodes (5-8) will start to blink. It will always show the last used setting. (7 = default first time)
- Press button 1 and the diode changes direction towards number 5. (After reaching diode 5 it will start again at number 8).

After Washes

8.diode Service now
7.diode Service after 25 washes (default installation)
6.diode Service after 50 washes
5.diode Service after 100 washes

- If no button is pressed for 5 sec. the chosen diode blinks 3 times to confirm the setting and jumps to step 2 time setting.

Step 2.

After Time

- One of the diodes will start to blink (1, 2, 3 or 4). The last used setting will always be shown (1 = default f rst time).
- Press button 1 and the diode changes direction towards 1. (After reaching diode 1, it will start again at number 4).

4.diode	Service after 1 month
3.diode	Service after 3 months
2.diode	Service after 6 months
1.diode	Service after 12 months (default installation)

- If no button is pressed for 5 sec. the chosen diode blinks 3 times to confirm the setting and jmp to step 3.

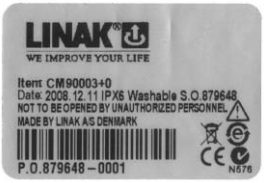
Step 3. (Display)

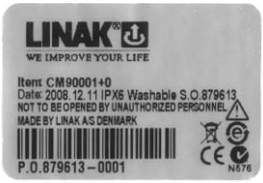
Display settings

- The diodes for wash (5 + 6 + 7 + 8) or the diodes for Time (1 + 2 + 3 + 4 will start to blink. The last used settings will always be shown.
- Press button 1 and the diodes change to light in 1 + 2 + 3 + 4 or 5 + 6 + 7 + 8.
  Diodes 5-8 Display setting after wash (default)
  Diodes 1-4 Display setting after Time
- If no button is pressed for 5 sec. the chosen setting blinks 3 times to confirm the choice.

- The Check Me system is ready for use. The chosen interval is not updated before you have followed the reset procedure.
- Pressing buttons 1 + 2 during the interval adjustment, will bring you back to the starting point again (last saved setting).

Labels

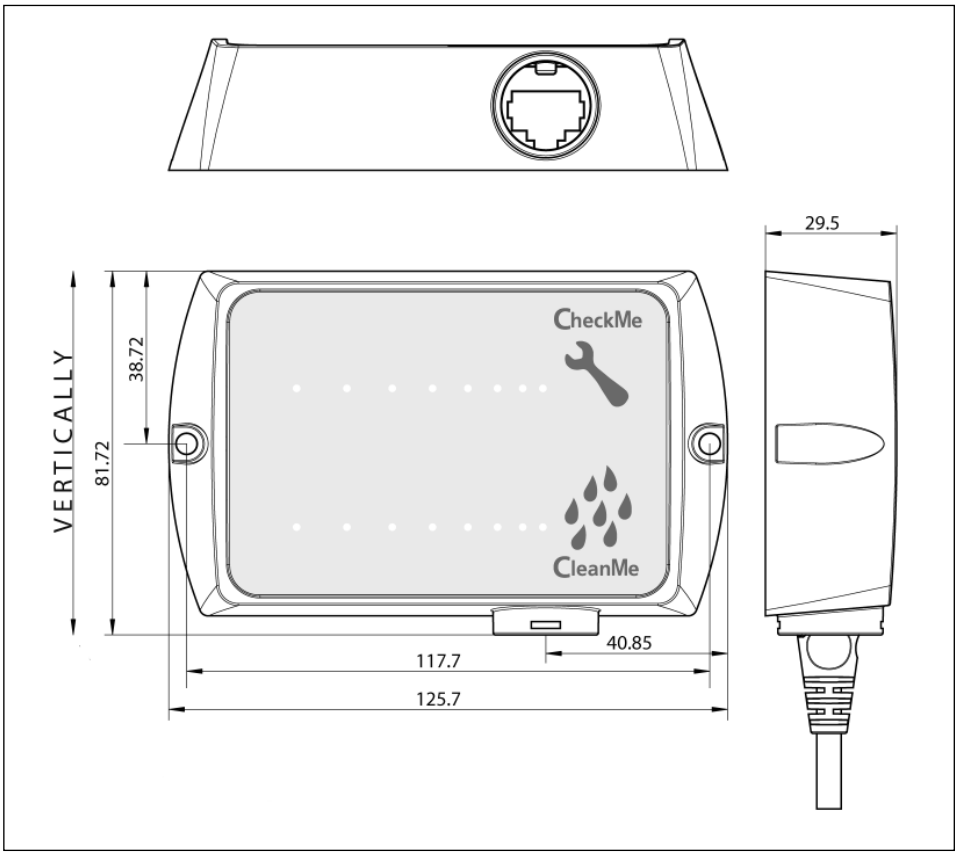




Battery Lifetime:
The built-in battery is able to supply the necessary power to keep the CleanMe / Check Me functional for 12 years, software timer controlled, from production date. The 12 years is based on the Clean Me / Check Me being used 80% on battery supply and 20% with mains supply. The lifetime can change according to the way that the Clean Me / Check Me is being used.

DRAWING APPENDIX

Clean Me Check Me:



DECLARATION OF CONFORMITY

LINAK A/S
Smedevænget 8
DK - 6430 Nordborg

hereby declares that LINAK Actuator System Accessory:

CME (CleanMe, CheckMe, CleanMe + CheckMe)

And

Control Box	CB6S	and / or
Control Box	CB16	and / or
Control Box	CB20	

complies with the EMC Directive: 2004/108/EC according to following standards:
EN 61000-4-2:1995+A1+A2, EN 61000-4-3:2006, EN 61000-4-4:2004,
EN 61000-4-5:1995+A1, EN 61000-4-6:1996+A1, EN 55011:1998+A1+A2 Class B

and complies with Low Voltage Directive 2006/95/EC according to the standard:
EN 60601-1:1990 (Medical electrical equipment) cl. 20.3 Dielectric strength (500 V DC)

Date: 2009-06-11

Signature:

(John Kling)

LINAK APPLICATION POLICY

The purpose of the application policy is to define areas of responsibilities in relation to applying a LINAK product defined as hardware, software, technical advice, etc. related to an existing or new customer application.

LINAK products as defined above are applicable for a wide range of applications within the Medical, Furniture, Desk and Industry areas. Yet, LINAK cannot know all the conditions under which LINAK products will be installed, used, and operated, as each individual application is unique.

The suitability and functionality of the LINAK product and its performance under varying conditions (application, vibration, load, humidity, temperature, frequency, etc.) can only be verified by testing, and shall ultimately be the responsibility of the LINAK customer using any LINAK product.

LINAK shall be responsible solely that the LINAK products comply with the specifications set out by LINAK and it shall be the responsibility of the LINAK customer to ensure that the specific LINAK product can be used for the application in question.

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